Complete if Known Substitute for form 1449/PTO Application Number 10/566,263 Filing Date September 28, 2006 INFORMATION DISCLOSURE First Named Inventor Jeffrey RUBERTI STATEMENT BY APPLICANT Art I Init 1796 (Use as many sheets as necessary) William K. CHEUNG Attorney Docket Number 20780-016 Sheet of 6 1

			U.S. PATENT DO	CUMENTS	
Examiner Cite		Document Number	Publication Date Name of Patentee or MM-DD-YYYY Applicant of Cited Document	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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/C.B./	A1	3,875,302	04/01/1975	Inoue	
	A2	4,472,542	09/18/1984	Nambu	
1	A3	4,663,358	05/05/1987	Hyon	
	A4	4,772,287	09/20/1988	Ray	
	A5	4,904,260	02/27/1990	Stoy	
1	A6	5,047,055	09/10/1991	Bao	
\top	A7	5,071,437	12/10/1991	Steffee	
\top	A8	5,260,066	11/09/1993	Wood	
1	A9	5,288,503	02/22/1994	Wood	
1	A10	5,534,028	07/09/1996	Bao,	
\top	A11	5,705,296	01/06/1998	Kamauchi	
+	A12	5,731,005	03/24/1998	Ottoboni	
+	A13	5,880,216	03/09/1999	Tanihara	
_	A14	5,976,186	11/02/1999	Bao	
+	A15	5,981,826	11/09/1999	Ku	
+	A16	6,231,605	05/15/2001	Ku	
\top	A17	6,264,695	07/24/2001	Stoy	
\top	A18	6,268,405	07/31/2001	Yao	
1.	A19	2004/0171740	09/02/2004	Ruberti	
W	A20	2004/0092653	05/13/2004	Ruberti	

			FOREIGN PATENT	DOCUMENTS		
Examiner initials*	Oite No.1	Foreign Patent Document Country Code ² Number ⁴ Kind Code ^{58 Annee}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	- T ^e
/C.B./	B1	WO 01/12107 Al	02/22/2001	LAMBRECHT	English	
	B2	WO 02/054978 A2	07/18/2002	LAMBRECHT	English	
-	ВЗ	JP 04 338326A	11/25/1992	OKAMURA	W/English Translation	
	B4	JP 03215417A	09/20/1991	YAMAUCHI et al.	W/English Translation	
\mathbb{V}	B5	EP 1229873	08/14/2002	MARCOLONGO	English	

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Substitute .	101 101111 1 1 1 1 1 1 0			Application Number	10/566,263	
				Filing Date	September 28, 2006	
	NEORMATIO	N D	ISCLOSURE	First Named Inventor	Jeffrey RUBERTI	
				Art Unit	1796	
STATEMENT BY APPLICANT (Use as many sheets as necessary)				Examiner Name	William K. CHEUNG	
Sheet	2	of	6	Attorney Docket Number	20780-016	

		NON PATENT LITERATURE DOCUMENTS	T ²		
Initials* No.3		clude name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, jeurnal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			
/C.B./	C1	AAOS, Musculoskeletal Conditions in the U.S., Feb. 1992-1988, 1992, AAOS			
ı	C2	Bao, Q.B., & Yuan, H. A., "Nucleus Replacement," Spine, Vol. 27, No. 11, 2002, 1245- 1247			
	C3	Bao, Q. & Yuan, H.A, "Prosthetic Disc Replacement: The Future?," Clinical Orthopaedics and Related Research, No. 394, pp 139-145, 2002			
	C4	Zeegers, W. S., et al, "Artificial disc replacement with the modular type SB Charit III: 2-year results in 50 prospectively studied patients," Eur Spine J, 8:210-217, 1999			
	C5	Wiesel, S.W. et al, "Industrial Low-Back Pain-A Prospective Evaluation of a Standardized Diagnosite and Treatment Protocol," SPINE, Vol. 9, No. 2, 199-203, 1984			
	C6	Vago, R., "Novel Natural Materials for Bone Substitutes and Hard Tissue Remodeling, http://www.bgu. ac. il/bgn/bone.html			
	C7	Bao, Q. et al, "The artificial disc: theory, design and materials," Biomaterials Vol. 17, No. 12, (1996) 1157-1167			
	C8	Urushizaki, F. et al, "Swelling and mechanical properties of poly(vinyl alcohol) hydrogels," International Journal of Pharmaceutics, 58 135-142, 1990			
	C9	UPMC Surgeons Implanting Metal Cages into the Spine to Treat Chronic Low Back Pain, Neurosurgery News, 1999, University of Pittsburgh			
	C10	Takeshita, H. et al, "Gelation Process and Phase Separation of PVA Solutions as Studied by a Light Scattering Technique," Macromolecules 32, 7815-7819, 1999			
	C11	Oka, M. et al, "Development of artificial articular cartilage," Proc Instn Mech Engrs Vol. 214 Part H. 59-68, 2000			
	C12	Onuki, A. & Puri, S., "Spinodal decomposition in gels," Physical Review E, Vol. 59, No. 2, Feb. 1999, R1331-R1334			
	C13	Mike, C., "FDA Approves Bone Graft," 2002, http://www.news.wisc.edu/view.html?get"7640			
	C14	Takeshita, H. et al, "Small-angle neutron scattering studies on network structure of transparent and opaque PVA gels," Physica B 311 (2002) 78-83			
1	C15	Lozinsky, V. I. et al, "Swelling behavior of poly(vinyl alcohol) cryogels employed as matrices for cell immobilization), Enzyme Microb. Technol, Vol. 18, 561-569, 1996			
-V	C16	Juarez, K.K. & An, H.S., "Artificial Disc Replacement, Spineuniverse.com			

Examiner Signature	Date Considered	
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Examiner Initials*	Cite Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposiu catalog, etc.), date, page(s), volume-issue number(s), publisher, eity and/or country where published.					
/C.B./	C17	Kawanishi K. et al, "Thermodynamic consideration of the sol-gel transition in polymer solutions," 35 th Annual Meeting of the Society of Polymer Science, Japan, 1986				
	C18	"New Implants Offer Relief of Spine 2001, Medical Device and Diagnostic Industry				
	C19	Takeshita, H., et al, "Spinodal Decomposition and Syneresis of PVA Gel, Macromolecules 2001, 34, 7894-7898				
	C20	Diwan, A. D. et al, "Current Concepts in Intervertebral Disk Restoration," Tissue Engineering in Orthopedic Surgery, Vol. 31, No. 3, pp 453-464, July 2000				
	C21	Peppas, N. A. et al, "Physicochemical Foundations and Structural Design of Hydrogels in Medicine and Biology," Annu. Rev. Biomed. Eng., 02:9-20, 2000				
	C22	Willcox, P. J., et al. "Microstructure of Poly(vinyl alcohol) Hydrogels Produced by Freeze/Thaw Cycling," Journal of Polymer Science: Part B: Polymer Physics, Vol. 37, 3438-3454 (1999)				
	C23	Bray, J.C. & Merrill, E. W., "Poly(vinyl alcohol) Hydrogels for Synthetic Articular Cartilage Material, Biomed. Mater. Res., Vol. 7, pp. 431-443 1973				
	C24	Stammen, J. A., et al., "Mechanical properties of a novel PVA hydrogel in shear and unconfined compression," Biomaterials, 2001 Apr 22 (8), 799-806, abstract only				
	C25	Bray, J.C. & Merrill, E. W., "Poly(vinyl Alcohol) Hydrogels. Formation by Electron Beam Irradiation of Aqueous Solutions and Subsequent Crystallization," Journal of Applied Polymer Science, Vol. 17, pp 3779-3794, 1973				
	C26	Hong, P, et al, "Solvent Effect on Structural Change of Poly(vinyl alcohol) Physical Gels," Journal of Applied Polymer Science, Vol. 69, 2477-2486 (1998)				
	C27	Hong, P. et al, "Effects of Mixed Solvent on Gelation of Poly(vinyl alcohol) Solutions," Journal of Applied Polymer Science, Vol 79, Issue: 6, Date: 7 February 2001, Pages: 1113-1120				
	C28	Hassan C. M. & Peppas N. A., "Structure and Morphology of Freeze/Thawed PVA Hydrogels," Macromolecule, Vol. 33, No. 7, 2472-2479, 2000				
	C29	Griffith, S. L. et al, "A Multicenter Retrospective Study of the Clinical Results of the LINK" SB Charite Intervertebral Prosthesis," SPINE, Vol. 19, No. 16, 1842-1849, 1994				
, ,	C30	Flory, P.J., "Principles of Polymer Chemistry, 1953, Ithaca and London: Cornell University Press				
V	C31	de Gennes, P.G., "Scaling Concepts in Polymer Physics," First ed. 1979: Cornell University Press. 72, 113-114				

Examiner Signature	Date Considere	d

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/C.B./	C32	Choi, J. H., et al., "Rheological Properties of Syndiotacricity-Rich Ultrahigh Molecular Weight Poly(vinyl alcohol) Dilute Solution," Journal of Applied Polymer Science, Vol. 82, 569-576 (2001)				
1	C33	Doehring, T.C. et al, "Cyclic Load-Displacement Characteristics of Lumber Functional Spinal Units," 46 th Annual Meeting, Orthopaedic Research Society, March 12-15, 2000				
	C34	Damshkaln, L. G., et al, "Study of Cryostructurarion of Polymer Systems. XV. Freeze- Thaw-Induced Formation of Cryoprecipitate Matter from Low-Concentrated Aquenous Solutions of Poly(vinyl alcohol), Journal of Applied Polymer Science, Vol. 74, 1978-1986 (1999)				
	C35	Darwis, D., et al, "Characterization of poly(vinyl alcohol) hydrogel for prosthetic intervetebral disc nucleus," Radiation Physics and Chemistry 63 (2002) 539-542				
	C36	Gomes, K. et al, "The Effect of Dehydration History on Associating Hydrogels for Nucleus Pulposus Replacement," Society for Biomaterials, 28 th Annual Meeting Transactions, 2002				
	C37	Hassan C., M. et al, "Diffusional characteristics of freeze/fhawed poly(vinyl alcohol) hydrogels: Applications to protein controlled release from multilaminate devices," European Journal of Pharmaceutics and Biopharmaceutics 49 (2000) 161-165				
	C38	Elias, H.G., "Theta Solvents," Brandrup, J. and E. H. Immergut, Polymer Handbook 3rd Ed., John Wiley & Sons, NY 1989				
	C39	Hassan, C., M., & Peppas, N.A., "Cellular PVA Hydrogels Produced by Freeze/Thawing," Journal of Applied Polymer Science, Vol. 76, 2075-2078 (2000)				
	C40	Lozinsky, V. I., et al, "Study of Cryostructuration of Polymer Systems, XIV. Poly(vinyl alcohol) Cryogels: Apparent Yield of the Freeze-Thaw-Induced Gelation of Concentrated Aqueous Solutions of the Polymer," Journal of Applied Polymer Science, Vol. 77, 1822-1831 (2000)				
	C41	Nakane, K., et al., "Properties and Structure of Poly(vinyl alcohol)/Silica Composites, Journal of Applied Polymer Science, Vol. 74, 133-138 (1999)				
V	C42	Hassan, C., M. et al., "Modeling of crystal dissolution of poly(vinyl alcohol) gels produced by freezing/thawing process," Polymer 41 (2000) 6729-6739				

ı	Signature	Considered	
	Examiner	Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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/C.B./	C43	Hickey, A. S. & Peppas N.A., "Solute diffusion in poly(vinyl alcoholy/poly(acrylic acid) composite membranes prepared by freezing/thawing techniques," Polymer, Vol. 38 No. 24 1997 5931-5936				
1	C44	Li, J. K., et al, "Poly(vinyl alcohol) nanoparticles prepared by freezing-thawing process for protein/peptide drug delivery," Journal of Controlled Release 56 (1998) 117-126				
	C45	Lozinskii V. I. & Savina I. N., "Study of Cryostructuring of Polymer Systems: 22. Composite Poly(vinyl alcohol) Cryogels Filled with Dispersed Particles of Various Degrees of Hydrophilicity/Hydrophobicity," Colloid Journal, Vol. 64, No. 3, 2002, 336-343				
	C46	Lozinsky, V. I. & Damshkaln L. G., "Study of Cryostructuration of Polymer Systems, XVII. Poly(vinyl alcohol) Cryogels: Dynamics of the Cryotropic Gel Formation, Journal of Applied Polymer Science, Vol. 77, 2017-2023 (2000)				
	C47	Marolongo, M., et al, "Novel Hydrogel Copolymers for Intervertebral Disc Replacement," Sixth World Biomaterials Congress Transactions, 2000				
	C48	Mongia, N.K., et al, "Mucoadhesive poly(vinyl alcohol) hydrogels produced by freezing/thawing processes: Applications in the development of wound healing systems," J. Biomater. Sci, Polymer Edn, Vol. 7, No. 12, pp. 1055-1064 (1996)				
	C49	Narasimhan, B. & Peppas, N.A., "Molecular Analysis of Drug Delivery Systems Controlled by Dissolution of the Polymer Carrier," Journal of Pharmaceutical Sciences, Vol. 86, No. 3, March 1997				
	C50	Norton, B. K, et al, "Mechanical Evaluation of a Structural Hydrogel for Use as a Spinal Disc Nucleus," Sixth World Biomaterials Congress Transactions, 2000				
	C51	Ogata, N., et al., "Poly(vinyl alcohol)-clay and Poly (ethylene oxide)-clay Blends Prepared Using Water as Solvent," Journal of Applied Polymer Science, Vol. 66, 573-581 (1997)				
	C52	Peppas, N.A. & Stauffer, S. R., "Reinforced uncrosslinked poly (vinyl alcohol) gels produced by cyclic freezing-thawing processes: a short review," Journal of Controlled Release, 16 (1991) 305-310				
	C53	Strawhecker, K.E. & Manias E., "AFM of Poly(vinyl alcohol) Crystals Next to an Inorganic Surface," Macromolecules, 2001, 34, 8475-8482				
	C54	Strawhecker, K.E. & Manias, E., "Structure and Properties of Poly(vinyl alcohol)INA+ Montmorillonite Nanocomposites," Chem. Mater, 2000, 12, 2943-2949				
V	C55	Takahashi, N., et al, "Effects of cononsolvency on gelation of poly(vinyl alcohol) in mixed solvents of dimethyl sulfoxide and water," Polymer 44 (2003) 4075-4078				

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/C.B./	C56	Wilke, H-J, et al, "Prosthetic Disc Nucleus Restores the Flexibility and Disc Height of a Disc After Nucleotomy," Sixth World Biomaterials Congress Transactions, 2000	
	C57	Yamaura K., et al, "Gels of Syndiotacticity-Rich Poly(vinyl Alcohol)-Water/Dimethyl Sulfoxide or - Water/Ethylene Glycol Solutions," Journal of Applied Polymer Science, Vol. 34, 2347-2354 (1987)	
	C58	Yamaura, K. et al., "Properties of Gels Obtained by Freezing/Thawing of Poly(vinyl Alcohol)/Water/Dimethyl Sulfoxide Solutions, Journal of Applied Polymer Science, Vol. 37, 2709-2718 (1989)	
	C59	Yokoyama, F., et al. "Morphology and structure of highly elastic poly (vinyl alcohol) hydrogel prepared by repeated freezing-and-melting," Colloid & Polymer Sci 264: 595-601 (1986)	
V	C60	Yu, Y, et al, "Preparation and properties of poly (vinyl alcohol) clay nanocomposite materials, Polymer 44 (2003) 3553-3560	

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